

-102-

We Claim:

- Sub  
a1
1. A method of detecting the presence of a target BS124 polynucleotide in a test sample, said method comprising:
- 5 (a) contacting the test sample with at least one BS124-specific polynucleotide or complement thereof; and
- (b) detecting the presence of said target BS124 polynucleotide in the test sample, wherein said BS124-specific polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of SEQUENCE ID NO
- 10 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.
2. The method of claim 1, wherein said target BS124 polynucleotide is attached to a solid phase prior to performing step (a).
- 15 3. A method for detecting mRNA of BS124 in a test sample, comprising:
- (a) performing reverse transcription with at least one primer in order to produce cDNA;
- 20 (b) amplifying the cDNA obtained from step (a) using BS124 oligonucleotides as sense and antisense primers to obtain BS124 amplicon; and
- (c) detecting the presence of said BS124 amplicon, wherein the BS124 oligonucleotides utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 1,
- 25 SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.
4. The method of claim 3, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).
- 30 5. The method of claim 3, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.
6. A method of detecting a target BS124 polynucleotide in a test sample suspected of containing said target, comprising:
- 35
- Sub  
a2

-103-

(a) contacting said test sample with at least one BS124 oligonucleotide as a sense primer and with at least one BS124 oligonucleotide as an anti-sense primer and amplifying to obtain a first stage reaction product;

5 (b) contacting said first stage reaction product with at least one other BS124 oligonucleotide to obtain a second stage reaction product, with the proviso that the other BS124 oligonucleotide is located 3' to the BS124 oligonucleotides utilized in step (a) and is complementary to said first stage reaction product; and

(c) detecting said second stage reaction product as an indication of the presence of the target BS124 polynucleotide, wherein the BS124 oligonucleotides  
10 utilized in steps (a) and (b) have at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.

15 7. The method of claim 6, wherein said test sample is reacted with a solid phase prior to performing one of steps (a), (b), or (c).

8. The method of claim 6, wherein said detection step comprises utilizing a detectable label capable of generating a measurable signal.  
20

9. The method of claim 8, wherein said detectable label is reacted to a solid phase.

25 10. A test kit useful for detecting BS124 polynucleotide in a test sample, comprising a container containing at least one BS124 polynucleotide having at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.  
30

11. A purified polynucleotide, or a fragment thereof, derived from a BS124 gene, wherein said polynucleotide is capable of selectively hybridizing to the nucleic acid of said BS124 gene and has at least 50% identity with a polynucleotide selected from the group consisting of (a) SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and  
35

SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.

Sub  
A2

Sub  
A3

complements thereof, and (b) fragments of SEQUENCE ID NO 1, SEQUENCE ID NO 2, and SEQUENCE ID NO 3.

12. The purified polynucleotide of claim 11, wherein said  
5 polynucleotide is produced by recombinant techniques.

13. The purified polynucleotide of claim 11, wherein said polynucleotide is produced by synthetic techniques.

10            14.    The purified polynucleotide of claim 11, wherein said  
polynucleotide comprises a sequence encoding at least one BS124 epitope.

15. A recombinant expression system comprising a nucleic acid sequence that includes an open reading frame derived from BS124 operably linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.

15. ✓ 16. A cell transfected with the recombinant expression system of claim

17. A BS124 polypeptide having at least 50% identity with an amino  
25 acid sequence selected from the group consisting of SEQUENCE ID NO 22,  
SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and  
fragments thereof.

18. The polypeptide of claim 17, wherein said polypeptide is produced  
30 by recombinant techniques.

19. The polypeptide of claim 17, wherein said polypeptide is produced by synthetic techniques.

35            20.    An antibody which specifically binds to at least one BS124  
epitope, wherein said BS124 epitope is derived from an amino acid sequence

-105-

having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.

- 5           21.     An assay kit for determining the presence of BS124 antigen or anti-BS124 antibody in a test sample, comprising a container containing a BS124 polypeptide having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.
- 10           22.     The assay kit of claim 21, wherein said polypeptide is attached to a solid phase.
- 15           23.     An assay kit for determining the presence of BS124 antigen in a test sample, comprising a container containing an antibody which specifically binds to a BS124 antigen which comprises at least one BS124 epitope.
- 20           24.     The kit of claim 23, wherein said antibody is attached to a solid phase.
- 25           25.     A method for producing a polypeptide comprising at least one BS124 epitope, said method comprising incubating host cells that have been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide, wherein said polypeptide comprises an amino acid sequence having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.
- 30           26.     A method for detecting BS124 antigen in a test sample suspected of containing said BS124 antigen, comprising:
- 35           (a)     contacting the test sample with an antibody or fragment thereof which specifically binds to at least one epitope of a BS124 antigen selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof, wherein said contacting is carried out for a time and under conditions sufficient for the formation of antibody/antigen complexes; and

(b) detecting the presence of said complexes as an indication of the presence of said BS124 antigen.

27. The method of claim 26, wherein said antibody is attached to a  
5 solid phase.

28. A method for detecting the presence of antibodies specific for a BS124 antigen in a test sample suspected of containing such antibodies, said method comprising:

10 (a) contacting the test sample with a BS124 polypeptide, wherein said BS124 polypeptide contains at least one BS124 epitope derived from an amino acid sequence or fragment thereof having at least 50% identity with an amino acid sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and  
15 fragments thereof, and further wherein said contacting is carried out for a time and under conditions sufficient to allow antigen/antibody complexes to form; and

(b) detecting the presence of said complexes as an indication of the presence of antibodies specific for a BS124 antigen.

20                    29.    The method of claim 28, wherein said BS124 polypeptide is  
attached to a solid phase.

30. A cell transfected with a nucleic acid sequence encoding at least one BS124 epitope, wherein said nucleic acid sequence is selected from the group consisting of SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 3, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and fragments or complements thereof.

31. A method for producing antibodies which specifically bind to  
30 BS124 antigen, said method comprising administering to an individual an isolated  
immunogenic polypeptide or fragment thereof in an amount sufficient to elicit an  
immune response, wherein said immunogenic polypeptide comprises at least one  
BS124 epitope and has at least 50% identity with a sequence selected from the  
group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23,  
35 SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.

-107-

32. A method for producing antibodies which specifically bind to BS124 antigen, comprising administering to an individual a plasmid comprising a sequence which encodes at least one BS124 epitope derived from a polypeptide having an amino acid sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.

Sub  
A7  
33. A composition of matter comprising a BS124 polynucleotide or fragment thereof, wherein said polynucleotide has at least 50% identity with a polynucleotide selected from the group consisting of (a) SEQUENCE ID NO 1, SEQUENCE ID NO 2, SEQUENCE ID NO 4, SEQUENCE ID NO 5, and complements thereof, and (b) fragments of SEQUENCE ID NO 1, SEQUENCE ID NO 2, and SEQUENCE ID NO 3.

34. A composition of matter comprising a polypeptide containing at least one BS124 epitope, wherein said polypeptide has at least 50% identity with a sequence selected from the group consisting of SEQUENCE ID NO 22, SEQUENCE ID NO 23, SEQUENCE ID NO 24, SEQUENCE ID NO 25, and fragments thereof.

35. The test kit of claim 10 further comprising a container with tools useful for collection of said sample, wherein said tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

36. The assay kit of claim 21 further comprising a container with tools useful for collection of said sample, wherein said tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

37. The test kit of claim 23 further comprising a container with tools useful for collection of said sample, wherein said tools are selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

Sub  
A8  
38. A gene, or a fragment thereof, which codes for a BS124 protein which comprises an amino acid sequence having at least 50% identity to SEQUENCE ID NO 22.

-108-

39. A gene, or a fragment thereof, comprising DNA having at least 50% identity with SEQUENCE ID NO 4 or SEQUENCE ID NO 5.

40. The method of claim 1, wherein presence of said target BS124 polynucleotide in said test sample is indicative of breast disease.

41. The method of claim 3, wherein presence of said amplicon is indicative of breast disease.

42. The method of claim 6, wherein presence of said second stage reaction product is indicative of breast disease.

43. The method of claim 26, wherein detection of said complexes is indicative of breast disease.

44. The method of claim 28, wherein detection of said complexes is indicative of breast disease.

add B9

add  
1017

Sub  
A9

6120.US.P1